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K964094

510(k) SUMMARY

The 510(k) summary information required by 21 CFR 807.92 is as follows:

- A. Classification name: Component, traction, invasive, or pin, fixation, threaded.
- Common/usual name: Unilateral mini-fixator, finger fixator, etc.
- Proprietary name: MINIFIX
- B. Substantial equivalence: Howmedica Hoffmann Fixation Pin System (K861766), Lima-LTO SEM Modular External Stabilizer (K880282) and others.
- C. Device description: The MINIFIX is a unilateral external fixator designed for use on small bones such as the metacarpal.
- D. Intended use: The MINIFIX is intended for use in the external fixation of fractures and/or reconstruction of small bones, including, but not limited to, metacarpal and metatarsal.
- E. Technological characteristics: The MINIFIX device

is similar to predicate devices in its design,  
function, and intended use.

The proposed device is quite simple in its  
configuration and design, therefore requires a  
minimum of instrumentation to install.

Submitted,  
**FERGUSON MEDICAL**  
Establishment Registration Number 2937794

A handwritten signature in cursive script, reading "Frank Ferguson", followed by a horizontal line.

Frank Ferguson  
Official Correspondent